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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,703	08/24/2001	Michel Samson	9409/2023D	1978

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,703

Applicant(s)

SAMSON ET AL.

Examiner

Jegatheesan Seharaseyon

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/24/01, 10/25/01, 8/14/02, 10/29/02, 5/23/.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. This Office Action in response to the preliminary amendment filed on 8/24/01 (Paper No: 10) and the supplemental preliminary amendments filed on 10/25/01 (Paper No: 5), 8/14/02 (Paper No: 9), 10/29/02 (Paper No: 11), 5/23/03 (Paper No: 12) and 6/5/03 (Paper No: 13). Claims 55-65 are pending. Claims 67-76 have been renumbered as 55-65 respectively under Rule 1.126.

Priority

2. Applicant is required to update the priority information in the first paragraph of the application with the current status.

Specification

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132. For example, the primer sequences in the specification lack SEQ ID Nos. In addition figures and the legends lack SEQ ID Nos.

A reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office.

Art Unit: 1647

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio

(<<http://www.uspto.gov/ebs/efs/downloads/documents.htm>>, EFS Submission User Manual - ePAVE)

2. Mailed to:U.S. Patent and Trademark Office,
Box Sequence, P.O. Box 2327Arlington, VA 22202.

3. Mailed by Federal Express, United Parcel Service or other delivery service to:U. S.
Patent and Trademark Office,
2011 South Clark PlaceCustomer Window, Box Sequence,
Crystal Plaza Two, Lobby, Room 1B03,
Arlington, Virginia 22202.

4. Hand Carried directly to the Customer Window at: 2011 South Clark PlaceCrystal
Plaza Two, Lobby, Room 1B03, Box Sequence,Arlington, Virginia 22202.

Drawings

4. The figures have been approved by the draftsman. However, the figure legends are not descriptive. For example, Figure 1 contain both A and B parts but lacks corresponding description. In addition, the various sequences in figure 2 and specification lack SEQ ID Nos.

Claim Objections

5. Claim 60 is objected to because it is dependent on claims that are not presented for examination. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6a. Claims 56-59 and 61-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

The specification discloses nucleotide sequence of SEQ ID No. 3 amino acid sequences of SEQ ID No. 6 and an antibody for human CCR5 presumably for SEQ ID No: 5 (see page 34, last paragraph). This meets the written description provisions of 35 USC 112, first paragraph. However, the specification as originally filed does not disclose an antibody that binds amino acid residues 185 to 215 of SEQ ID NO: 6 nor does it describes an antibody that binds to a polypeptide encoded by a nucleic acid comprising residues 792 to 884 of SEQ ID No: 3. It should be noted that the amino acids 185 to 215 of SEQ ID No: 6 are the result of a deletion and frame shift mutation in the wild type receptor. The claims as written, however, encompass antibodies that bind amino acid sequences which were not originally contemplated and fail to meet the written description provision of 35 USC 112, first paragraph because the written description is not commensurate in scope with the recitation of claims 56-59 and 61-65. The

Art Unit: 1647

specification does not provide adequate written description to support the genus encompassed by the instant claims.

In the supplemental preliminary amendments filed on the 5/23/03 (Paper No: 12) and 6/5/03 (Paper No: 13), Applicant has recited claims containing an antibody that binds amino acid residues 185 to 215 of SEQ ID NO: 6 and an antibody that binds to a polypeptide encoded by a nucleic acid residues 792 to 884 of SEQ ID No: 3 which are not described in the specification. Thus, these antibodies were not described in the original disclosure and constitute new matter.

Therefore, only the nucleotide sequence of SEQ ID No. 3 amino acid sequences of SEQ ID No. 6 and an antibody for human CCR5 presumably for SEQ ID No: 5, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus.

6b. Claims 56, 58, 61, 63 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.*

The specification discloses nucleotide sequence consisting of SEQ ID No. 3 amino acid sequence consisting of SEQ ID No. 6. However, the specification does not disclose all nucleotide sequence comprising SEQ ID No. 3 or amino acid sequence comprising of SEQ ID No. 6. The claims as written, however, encompass nucleotide

Art Unit: 1647

sequences encoding a protein and amino acids which were not originally contemplated and fail to meet the written description provision of 35 USC 112, first paragraph because the written description is not commensurate in scope with the recitation of claims 56, 58, 61, 63 and 65. The specification does not provide written description for all nucleotide and amino acid sequences contemplated. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

With the exception of nucleotide sequence consisting of SEQ ID No. 3 amino acid sequence consisting of SEQ ID No. 6, the skilled artisan cannot envision all the detailed structure of the claimed nucleotides encoding the polypeptide and amino acid sequences, regardless of the complexity or simplicity of the method of isolating the same. As a result, it does not appear that the inventors were in possession of the invention to use all nucleotides encoding the polypeptide and amino acid sequences as set forth in claims 56, 58, ~~60~~, 61, 63 and 65 or that any modulation will treat cardiovascular diseases. Claims 65 is rejected insofar as it depends on rejected claims 61 and 63.

Art Unit: 1647

7. The art made of record and not relied upon is considered pertinent to applicant's disclosure. Beretta et al. (U.S. Patent No. 6,153,431) teaches a purified and isolated nucleic acid encoding CCR5 variant protein which comprises the first two transmembrane of the wild type CCR5 but lacks transmembrane domains 3,4, 5, 6 and 7.

8. No claims are allowed.

Contact information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
June 13, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600